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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,053	12/07/2000	Robert Sullivan	13045-2US-1-	3285

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EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

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14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/719,053	Applicant(s) SULLIVAN ET AL.	
	Examiner Phuong Huynh	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) *1,2 and 4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-4 are pending.

2. Claims 1-2 and 4 stand withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to non-elected inventions. Applicant is reminded that in order to cancel non-elected inventions, a formal request must be made.

3. Claim 3 is being acted upon in this Office Action.

4. The following new grounds objection and rejection are necessitated by the amendment filed 1/30/03.

5. Claim 3 is objected to because "elecitng" is misspelled. It should have been "eliciting". Further, "a" is missing immediately after "being".

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling only for (1) an immunogenic composition comprising an antigenic fragment of a P34 protein wherein the fragment consisting of amino acid sequence selected from the group consisting of SEQ ID NO: 4 and 5 and a suitable pharmaceutically acceptable carrier for eliciting antibodies immune response for detection assay , **does not** reasonably provide enablement for *any* vaccine for electing any immunocontraceptive reaction in any male or female subject which comprises an antigenic amount of a protein being member of the Short Chain Dehydrogenase/Reductase family and having the amino acid sequence of a protein encoded by the nucleic acid sequence SEQ ID NO: 3 in association with a suitable pharmaceutically acceptable carrier for immunocontraceptive vaccine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in **scope** with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation.

The specification discloses only a p26h polypeptide, which is an acrosomal sperm protein as well as a member of the Short Chain Dehydrogenase/Reductase family, comprising the amino acid sequence of SEQ ID NO: 2 encoded by a polynucleotide of SEQ ID NO: 1. The specification further discloses two peptides consisting of SEQ ID NO: 4 and 5 and a polynucleotide of p34 comprising SEQ ID NO: 3. The specification discloses immunizing a subject with an antigenic fragment of p34 to generate antibodies for diagnosis of male and female infertility.

The specification does not teach how to make and use *any* vaccine for electing any immunocontraceptive reaction in any male or female subject mentioned above for immunocontraception because there is insufficient guidance as to the binding specificity of antibody generated from immunizing a protein encoded by the nucleic acid sequence of SEQ ID NO: 3. Further, there is no working example that the antibody to said protein encoded by the nucleic acid sequence of SEQ ID NO: 3 ever been made, much less the antibody can interfere with the binding of sperm to the zona pellucida in vitro or in vivo. Finally, there is no in vivo working example demonstrating that resulting antibodies generated from a protein encoded by SEQ ID NO: 3 are effective as a contraceptive vaccine.

Kuby *et al* teach that antibody epitopes (B cell epitopes) are not linear and are comprised of complex three-dimensional array of scattered residues which will fold into specific conformation that contribute to binding (See Kuby 1994, page 94, in particular). Immunization with a peptide fragment derived from a full-length polypeptide may result in **antibody specificity** that differs from the antibody specificity directed against the native full-length polypeptide.

Abaza *et al* teach that even a single amino acid substitution outside the antigenic site can exert drastic effects on the reactivity of a protein with monoclonal antibody against the site (See abstract, in particular). Even if the vaccine is limited to the peptide consisting of SEQ ID NO: 4

and 5, there is no in working example that the antibody generated from the peptide can interfere with the binding of sperm to the zona pellucida in vitro or in vivo. Again, there is no in vivo working example demonstrating that resulting antibodies generated from the peptide selected from the group consisting of SEQ ID NO: 4 and 5 are effective as a contraceptive vaccine.

A vaccine in the absence of in vivo data is unpredictable for the following reasons: (1) the antibody generated from the protein may not interfere with the binding of sperm to the zona pellucida ; (2) the protein encoded by the nucleic acid of SEQ ID NO: 3 may not reach the target area because, i.e. the protein may not be able to cross the mucosa or the protein may be adsorbed by fluids, cells and tissues where the protein has no effect; and (3) other functional properties, known or unknown, may make the protein unsuitable for in vivo therapeutic use, i.e. such as adverse side effects prohibitive to the use of such treatment. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

For these reasons, it would require undue experimentation of one skilled in the art to practice the claimed invention. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

In re wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the decision of the court indicates that the more unpredictable the area is, the more specific enablement is necessary. In view of the quantity of experimentation necessary, the lack of in vivo working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

8. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of *any* vaccine for electing any immunocontraceptive reaction in any male or female subject which comprises an antigenic amount of a protein being member of the Short Chain Dehydrogenase/Reductase family and having the amino acid sequence of a protein encoded by the nucleic acid sequence SEQ ID NO: 3 in association with a suitable pharmaceutically acceptable carrier for immunocontraceptive vaccine.

The specification discloses only a p26h polypeptide, which is an acrosomal sperm protein as well as a member of the Short Chain Dehydrogenase/Reductase family, comprising the amino acid sequence of SEQ ID NO: 2 encoded by a polynucleotide of SEQ ID NO: 1. The specification further discloses two peptides consisting of SEQ ID NO: 4 and 5 and a polynucleotide of p34 comprising SEQ ID NO: 3. The specification discloses immunizing a subject with an antigenic fragment of p34 to generate antibodies for diagnosis of male and female infertility.

There is inadequate written description about the binding specificity of the antibody generated from a protein encoded by the nucleic acid sequence SEQ ID NO: 3, in turn, the vaccine for eliciting any immunocontraceptive reaction in any male or female subject. Further, the specification on page 2 discloses an immunocontraceptive vaccine for a male or female subject which comprises administering an antigenic fragment of a P34 protein consisting of an amino acid sequence such as SEQ ID NO: 4 and SEQ ID NO: 5. There is no disclosure of a vaccine as set forth in claim 3. Given the lack of a written description about the vaccine as set forth in claim 3, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.*

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

9. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection**.

The vaccine as set forth in claim 3 represents a departure from the specification and the claims as originally filed because the specification and the claim as originally filed do not provide a clear support for the a vaccine comprising the protein encoded by the nucleic acid of SEQ ID NO: 3. Further, Applicants have not pointed out the support for the vaccine as set forth in claim 3 comes from.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

11. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "in association with" in claim 3 is ambiguous and indefinite because it is not clear if protein encoded by the nucleic acid sequence SEQ ID NO: 3 is conjugated to the carrier or simply being with a carrier (unconjugated). If it is meant to be unconjugated to a carrier, it is suggested that the claim be amended to recite "...and a suitable pharmaceutically acceptable carrier". Correction is required.

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any

inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

15. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
April 7, 2003

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600